UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-12257
THIS DOCUMENT RELATES TO: **ALL ACTIONS**	

MEMORANDUM AND ORDER RE: MOTION FOR CLASS CERTIFICATION

August 16, 2005

Saris, U.S.D.J.

I. INTRODUCTION

In this proposed massive class action, thirteen plaintiffs claim that forty-two defendant pharmaceutical manufacturers fraudulently and grossly inflate the prices to consumers of many drugs by misstating the "Average Wholesale Prices" ("AWPs") of their drugs in industry publications. These overstated AWPs allegedly cause beneficiaries of the Medicare Part B program, other consumer-patients, and third-party payors ("TPPs"), such as private health insurers, private health and welfare plans, and self-insured employers, to overpay for prescription drugs.

In this stage of the litigation, plaintiffs seek to certify three nationwide classes encompassing consumers and TPPs who allegedly paid inflated prices for 132 brand-name and generic prescription drugs on the basis of published, fraudulent AWPs.[1]

[1] This motion encompasses 132 of the 321 drugs identified in the Second Amended Master Consolidated Complaint ("SAMCC").

Seventeen of the drugs at issue are reimbursed under Medicare Part B. The three proposed classes are the "physician-administered class," "the self-administered and specialty pharmacy class," and the "RICO class for self-administered and specialty drugs." The proposed class period is 1991 to the present.

Defendants argue that the proposed classes, involving millions of people and 11,000 TPPs, should not be certified because common factual and legal issues do not predominate and the classes are not manageable. They highlight differences among the plaintiffs, among the defendants, among the 132 identified drugs (the "AWPIDs"), and among methods of reimbursement.

Plaintiffs allege violations of RICO, 18 U.S.C. § 1962(c), claiming that each manufacturer was engaged in an unlawful racketeering enterprise with each of four pharmacy benefit managers ("PBMs") - AdvancePCS; Caremark, Rx, Inc.; Express

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The Court divided this multi-district litigation into two tracks, fast-track ("Track One") and normal-track ("Track Two"). Plaintiffs seek certification of three classes covering all of the Track One defendants' drugs named in the SAMCC. The Track One defendants are AstraZeneca PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. ("AstraZeneca"); Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc. ("the BMS Group"); GlaxoSmithKline, P.L.C., SmithKline Beecham, P.L.C., and GlaxoWellcome, Inc. ("the GSK Group"); Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products, L.P., McNeil-PPC, Inc., and Ortho Biotech ("the Johnson & Johnson Group"); and the Schering-Plough Corporation and Warrick Pharmaceuticals Corporation ("the Schering Plough Group").

Scripts, Inc.; and Medco Health Solutions, Inc. (Count II). They also assert common law civil conspiracies to violate state consumer protection laws, state fraud laws, and state Medicare anti-kickback laws (Count IX). Finally, they claim that defendants committed fraud under state consumer protection laws by sending the AWPs to third party publishers (Count IV).[2]

Plaintiffs propose a two-phase trial, with issues of liability, causation, and aggregate (or per drug) damages adjudicated in Phase I by a jury, and issues of individualized damages for each class member adjudicated in Phase II. Plaintiffs describe Phase II as an administrative process, albeit one in which defendants may challenge class members' proofs of claims, if necessary, in a jury trial.

After hearing and review of the extensive briefing, the reports of the parties' experts,[3] and the report of independent expert Ernst R. Berndt, a professor of applied economics at the

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[2] Count I of the SAMCC, which alleged a RICO enterprise involving three publishers (Thompson Medical Economics, publisher of the Drug Topics Red Book; First Data Bank ("FDB"), publisher of the Blue Book; and Facts & Comparisons, Inc., publisher of the Medi-Span Master Drug Data Base), was dismissed. In re Average Wholesale Price Litig., 307 F. Supp. 2d 196, 203-05 (D. Mass. 2004). The plaintiffs are not pressing Count III, seeking declaratory relief pursuant to 28 U.S.C. § 2201. Counts V to VIII and X pertain to the alleged Together Card Rx conspiracy to violate the antitrust laws, and are proceeding on Track Two of this litigation.

[3] The parties filed over twenty-two boxes of exhibits in relation to this motion, in addition to dozens of briefs and expert reports.

Sloan School of Management, Massachusetts Institute of Technology, I rule as follows: (1) the association plaintiffs do not have standing to assert claims of consumer-beneficiaries who make co-payments under Medicare Part B or who make private co-insurance payments for physician-administered drugs under private health insurance plans; (2) TPPs are not adequate or typical class representatives for Medicare Part B consumers; (3) a nationwide class of Medicare Part B beneficiaries meets the remainder of the requirements of Fed. R. Civ. P. 23(a) and 23(b)(3); (4) plaintiffs may amend the SAMCC to propose individual class plaintiffs who are Medicare Part B beneficiaries; (5) the Court **DENIES** the motion to certify a **nationwide** class of TPPs that provide MediGap-type supplemental insurance but certifies a **statewide** class in Massachusetts; (6) the Court **DENIES** the motion to certify a **nationwide** class of TPPs and consumers that pay for physician-administered drugs outside the Medicare Part B context but certifies a **statewide** class in Massachusetts; (7) the motion to certify nationwide classes of TPPs and consumers paying for self-administered drugs is **DENIED**.[4]

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[4] The Court has addressed the same scheme in numerous prior decisions. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172 (D. Mass. May 13, 2003); Montana v. Abbot Labs., 266 F. Supp. 2d 250 (D. Mass. June 11, 2003); In re Pharm. Indus. Average Wholesale Price Litig., 309 F. Supp. 2d 165 (D. Mass. Jan. 9, 2004); In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 190 (D. Mass. Jan. 9, 2004); In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196 (D. Mass. Feb. 24, 2004); In re Pharm. Indus.

II. PROPOSED CLASSES

Plaintiffs seek certification of the following classes, with respect to the drugs identified in the SAMCC, Attachment A, for defendants AstraZeneca, the BMS Group, the GSK Group, the Johnson & Johnson Group, and the Schering Plough Group:

> **[1] Physician-Administered Drugs Class (Medicare Part B Co-Pay and Private System Physician-Administered Drugs)**
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> All persons or entities in the United States and its territories who (i) paid all or a portion of the co-insurance under Medicare Part B for an AWPID during the Class Period, and/or (ii) reimbursed another for a physician-administered AWPID under a contract that expressly uses AWP as a pricing standard, along with all individual persons who paid coinsurance (i.e., co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.
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> **[2] Self-Administered and Specialty Pharmacy Drugs Class (Third-Party and Co-Payor Class for Self-Administered Drugs)**
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> All persons or entities in the United States and its territories who reimbursed another for any self-administered AWPID, or for any AWPID which was distributed through a specialty pharmacy, under a contract that expressly uses AWP as a pricing standard, along with all individual persons who paid coinsurance (i.e., co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

Average Wholesale Price Litig., 321 F. Supp. 2d 187 (D. Mass. June 10, 2004); In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d 165 (D. Mass. Sept. 30, 2004); Massachusetts v. Mylan Labs., 357 F. Supp. 2d 314 (D. Mass. Feb. 4, 2005).

> The foregoing class is further subdivided into the following subclasses:
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> (a) brand-name sub-class; and
> (b) generic the sub-class [sic]
>
> **[3] RICO Class for Self-Administered and Specialty Drugs**
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> All persons or entities in the United States and its territories who reimbursed another for any self-administered AWPID, or for any AWPID which was distributed through a specialty pharmacy, under a contract with Caremark, AdvancePCS, Express Scripts and/or Medco (or their predecessors), which contract expressly uses AWP as pricing [sic] standard, along with all individual persons who paid coinsurance (i.e. co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.
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> The foregoing class is further subdivided into the following subclasses:
> (a) brand-name sub-class; and
> (b) generic the sub-class [sic]

(Am. Mot. for Class Cert. 3-4.)

III. FACTUAL BACKGROUND

For background about the structure of the pharmaceuticals market, the Court has relied on the expert reports of the parties, the tutorials on the structure of the pharmaceutical markets, and the excellent report written by Professor Ernst Berndt.[4] As is appropriate on a motion for class certification,

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[4] Professor Berndt's report, which provides substantially more detail than this Order about the structure and history of the pharmaceuticals market, is available on the electronic docket at entry number 1384. He supplemented this report with a short memorandum on August 9, available at entry number 1639. The

the Court has generally treated the allegations of the SAMCC as true, but has also peered behind the SAMCC to determine what issues are susceptible to resolution via class treatment. See Waste Mgt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 298 (1st Cir. 2000).

A. AVERAGE WHOLESALE PRICE AND THE SPREAD

Throughout the class period, from 1991 to the present, AWP has been the pricing benchmark for most pharmaceutical sales in the United States. (Hartman Decl. attach. D ¶¶ 29-30; Schondelmeyer ¶ 36.) It is akin to a sticker price for automobiles, setting the pricing baseline. (Hartman Decl.

Court also received the reports of plaintiffs' experts, Dr. Raymond Hartman, an economist and a director at Greylock McKinnon Associates litigation consulting firm with extensive teaching and research experience; Professor Stephan Schondelmeyer, an economist at the University of Minnesota who is head of the Department of Pharmaceutical Care & Health Systems; and Professor Richard Frank, a professor of health economics at Harvard Medical School; and the reports of defendants' experts, Steven Young, the Managing Director of Huron Consulting Group's Healthcare and Higher Education Consulting practice; Dr. Eric Gaier, a partner at Bates White, a professional services firm that specializes in economic analysis; Dr. Robert Navarro, a pharmacist, an expert in pharmacy benefit managers, and president of the consulting firm NavarroPharma LLC; and Professor Halbert White, a professor in economics at the University of California, San Diego, who specializes in econometrics. The Court also attended a two-day tutorial hearing presented by plaintiffs' expert Dr. Meredith Rosenthal, an assistant professor of Health Economics and Policy at the Harvard School of Public Health, and defendants' experts Professor Fiona Scott Morton of the Yale School of Management (who spoke on a DVD tutorial but not at the hearing) and Dr. Gregory Bell, a Group Vice President at the Charles River Associates consulting firm.

attach. D n.1.) Private publications such as the Drug Topics Red Book, the First Data Bank Blue Book, and the Medi-Span Master Drug Data Base list the AWPs. For each drug, the publications list one or more eleven-digit National Drug Code numbers ("NDCs"), which convey information such as dosage, package size, and manufacturer; each NDC of a drug may have its own AWP.[5]

Dr. Berndt states:

> To knowledgeable industry observers, it has long been widely understood that in the U.S. pharmaceutical industry, the term "average wholesale price" [AWP] is a misnomer: it is not a measure of prices generally paid by wholesalers to manufacturers, it is not a measure of prices frequently paid by retail or mail order pharmacies to wholesalers, nor is it some average of these.

(Berndt ¶ 14.) Nonetheless, "real and understandable" confusion still remains, even within the industry, as to what AWP is. (Berndt ¶ 81.) Mockingly referred to as "Ain't What's Paid," AWP has been defined in the literature in various ways. (Berndt ¶ 16 (citing Bill Alpert, Hooked on Drugs: Why do Insurers Pay Such Outrageous Prices for Pharmaceuticals?, Barrons, June 1996, at 3).) For example, according to the American Society of Consultant Pharmacists' website, First Data Bank stated as late as 2000 that AWP is "the average wholesale price. That is, AWP is the average of the prices charged by the national drug

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[5] For example, Appendix A to the SAMCC lists 40 different NDCs for the compound Dextrose, manufactured by B. Braun McGaw, with AWPs ranging from $15.98 to $2,032.32.

wholesalers for a given product (NDC). The operative word is average." (Berndt ¶ 78.) Other recent documents continue to state that AWP is an actual average of prices (Berndt ¶ 80), even as government reports and other sources have stated that AWP is not an accurate measure of wholesale prices (Berndt ¶¶ 65-67).

Related to the AWP is a drug's Wholesale Acquisition Cost ("WAC"), which also is listed in publications.[6] WAC is understood to be the price at which a pharmaceutical firm typically sells a drug to wholesalers. (Berndt ¶ 15.) The WAC for single-source drugs correlates with the AWP over the life of a drug.[7] Typically, the AWP for a brand-name, self-administered drug is 20% or 25% above WAC. (Schondelmeyer ¶ 89; Berndt ¶ 15.) In the generic drug context the relationship is less predictable, with AWPs sometimes reaching 50% to 100% above WAC. (Schondelmeyer ¶ 92.)

In almost every sale of prescription drugs, reimbursement from the government or TPP is based on AWP, WAC, or a discount

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[6] Some defendants claim that they send data items other than WACs to publishers (such as Wholesale List Prices, "WLPs," in the case of Bristol-Myers Squibb), but these appear to be functional equivalents of WAC.

[7] A multi-source drug, as opposed to a single-source drug, is a drug for which generic versions exist. See 42 U.S.C. § 1396r-8 (defining multi-source drugs in the context of the Best Prices rebate program). The parties have noted that in other contexts there is a difference between a generic drug and a multi-source drug, but that the difference is irrelevant to this case.

from one of these numbers (e.g., AWP minus 15%). As plaintiffs' expert Hartman states, "The AWP, or its formulaic equivalent the WAC (Wholesale Acquisition Cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs." (Hartman Rebuttal ¶ 3.) However, manufacturers actually sell drugs to providers like pharmacies and doctors at prices far below AWP and WAC. This creates a "spread" between the price healthcare providers pay to acquire drugs from wholesalers or manufacturers (the average acquisition cost, "AAC") and the reimbursement rate paid by TPPs, the government, and consumers making co-insurance payments or paying the entire cost of a drug. This spread can reach into the hundreds of dollars and thousands of percentage points:

Drug	Abbott's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Spread
Acetylcysteine	$ 35.87	$ 21.90	$ 13.97	64%
Acyclovir	$1047.38	$ 349.05	$ 698.33	200%
Amikacin Sulfate	$ 995.84	$ 125.00	$ 870.84	697%
Calcitriol (Calcijex)	$1390.66	$1079.00	$ 311.66	29%
Cimetidine Hydrochloride	$ 214.34	$ 35.00	$ 179.34	512%
Clindamycin Phosphate	$ 340.52	$ 75.35	$ 265.17	352%
Dextrose	$ 239.97	$ 3.91	$ 236.06	6,037%
Dextrose Sodium Chloride	$ 304.38	$ 1.93	$ 302.45	15,671%

Diazepam	$ 28.50	$ 2.03	$ 26.47	1,304%
Furosemide	$ 74.52	$ 14.38	$ 60.14	418%
Gentamicin Sulfate	$ 64.42	$ .51	$ 63.91	12,531%
Heparin Lock Flush	$ 38.30	$ 13.60	$ 24.70	182%
Metholprednisolone Sodium Succinate	$ 34.08	$ 2.30	$ 31.78	1,382%
Sodium Chloride	$ 670.89	$ 3.22	$ 667.67	20,735%
Tobramycin Sulfate	$ 150.52	$ 2.94	$ 147.58	5,020%
Vancomycin Hydrochloride	$ 382.14	$ 4.98	$ 377.16	7,574%

In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d at 178 (quoting Complaint ¶ 190).

The gravamen of the fraudulent scheme alleged in the SAMCC is that defendant manufacturers send publishers their AWPs (or their WACs), knowing that TPPs and government payors consider them indicators of prices to providers. Defendants know that class members will make reimbursement payments based on those prices. In fact, plaintiffs allege, for the 321 identified drugs, the AWPIDS, AWPs are neither the true average prices charged by wholesalers nor the price measure "expected" by the market (e.g., AWP minus 16% to 33% is the cost to providers). Instead, defendants (or wholesalers) sell a drug to retailers at a net price often significantly below the expected "AWP minus 16% to 33%" threshold by utilizing hidden discounts, off-invoice rebates, free samples, education grants, and other promotional

means that are not reflected in the list price. Defendants do so to increase their market share or sales, at a cost to the end-payor. Under plaintiffs' theory, class members have been defrauded by intentionally false misrepresentations as to AWP that permit retailers and intermediaries like PBMs to retain the benefits of price reductions. Plaintiffs allege that the scheme led to huge profits for drug companies and doctors at the expense of insurers and their beneficiaries.

B. REIMBURSEMENT FOR DRUGS

An analysis of the methods of drug reimbursement is essential to understanding the viability of the three proposed classes, which reflect two significantly different methods of distributing drugs. First, physician-administered drugs (mostly brand-name drugs) are generally sold to consumer-patients by physicians, who are reimbursed by the government Medicare Part B program and by private sector TPPs. Consumer-patients typically make "co-insurance" payments for these drugs, meaning they pay a portion of the cost of the drug based on a percentage of AWP, rather than a flat co-payment. The plaintiffs seek to include in the proposed class only consumer-patients who make co-insurance payments, not those who make flat co-payments.

Second, self-administered drugs (both brand-name and generic) are typically bought by a consumer through a retail or mail-order pharmacy, which is then sometimes reimbursed by a TPP

or PBM. Again, consumers who make percentage-based co-payments (but not those who make flat co-payments) are included in the proposed class. I address the different reimbursement schemes separately below.

1. Medicare Part B Coverage for Physician-Administered Drugs

Medicare spent a large and rapidly growing amount on prescription drugs throughout the class period. In 1998, Medicare spent $3.3 billion on prescription drugs. (Schondelmeyer ¶ 44.) This number grew to $8.4 billion by 2002. (Id.)

While Medicare generally did not cover the cost of self-administered prescription drugs during the proposed class period, it did cover some physician-administered drugs, including chemotherapies, inhalation therapies, end-state renal disease drugs, oral cancer drugs, and drugs used following organ transplants.[8] (SAMCC ¶ 144; Berndt ¶ 88.) Medicare Part B provided prescription coverage for approximately 450 drugs during this period.[9] (Berndt ¶ 88.) This set of drugs, known as "specialty pharmacy products," includes many brand-name drugs for which no effective therapeutic competition exists, making them

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[8] About half of all cancer patients are covered by Medicare. (Berndt ¶ 89.)

[9] The Medicare statute has since been amended to add a more extensive prescription drug benefit. No one has briefed the effect of the statute on the class, which is defined as 1991 to the present. I will not address its impact here.

very expensive -- some cost more than $10,000. (Berndt ¶¶ 89, 93.) Thirty-five of these drugs accounted for 90% of Medicare Part B spending on drugs. (Berndt ¶ 87.) Seventeen of the 132 drugs at issue in this litigation were reimbursed under Medicare Part B. (Rosenthal 4.)

AWP was the basis for drug reimbursement under Medicare Part B for most of the proposed class period. Under the fee-for-service program, Medicare Part B reimburses for drugs based on formulae set by federal statute and federal regulations.[10] See, e.g., 42 U.S.C. §§ 1395u(o), 1395l(s); 42 C.F.R. § 405.517. From 1992 to 1997, reimbursement for single-source brand-name drugs was set at the lesser of the estimated acquisition cost ("EAC") or AWP.[11] 42 C.F.R. § 405.517 (amended Nov. 2, 1998; Jan. 7, 2004; Nov. 15, 2004). The EAC was supposed to be measured through surveys conducted by regional Medicare administrators (termed "carriers"), who were to determine the usual and customary charge ("U&C") for a geographic area. Id. However, the carriers never conducted the surveys, and instead relied on AWPs. (Rosenthal 7.) For multi-source generic drugs,

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[10] Approximately 88% of patients in Medicare participate in the traditional, fee-for-service Medicare system. (Bell 18-19.) The other 12% participate in Medicare + Choice, a managed care system administered by commercial insurers. (Id.)

[11] Prior to 1992, reimbursement was based on the "reasonable charge" amount. (Berndt ¶ 92.) Regional carriers would examine the amount billed by a physician and pay it if it was deemed reasonable.

reimbursement was set at the lower of EAC or the "Maximum Allowable Cost" ("MAC"), where MAC is defined as the median of the AWPs of all generic forms of a drug. 42 C.F.R. § 405.517 (amended Nov. 2, 1998; Jan. 7, 2004; Nov. 15, 2004).

On January 1, 1998, the relevant statute and regulation were amended. Reimbursement for single-source drugs was changed to the lesser of (1) the billed charge on the Medicare claim form or (2) 95% of AWP. 42 U.S.C. § 1395u(o) (amended Dec. 8, 2003); 42 C.F.R. § 405.517. Reimbursement for generic drugs was changed to the lower of (1) the median of the AWPs of all generic forms of a drug or (2) the AWP of the least expensive brand-name drug. 42 U.S.C. § 1395u(o) (amended Dec. 8, 2003); 42 C.F.R. § 405.517. From January 1, 2004 to January 1, 2005, drugs were generally reimbursed at 85% of AWP, although reimbursement for certain drugs is particularly described in the applicable regulation. 42 U.S.C. § 1395u(o); 42 C.F.R. § 414.707. Since January 1, 2005, reimbursement for both single-source and multi-source drugs has been based on the Average Sales Price (the actual average manufacturer's sales price) of a drug as reported by manufacturers. 42 C.F.R. § 414.904 (for single-source drugs, "[t]he average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product").

Because the carriers never conducted the surveys of EACs,

AWP became the basis for most Medicare reimbursement. (Rosenthal 7.) The government utilized the AWPs listed in the pricing publications, which follow defendants' pricing instructions.[12]

Medicare pays 80% of the allowed amount of a covered drug, and the beneficiary is responsible for paying the other 20%. 42 U.S.C. § 1395l(a)(1)(S). Many beneficiaries have purchased private "MediGap" (or "wrap around") insurance, which pays all or some of this 20% co-payment. (Bell 35.) In 2000, approximately 85% of the approximately 40 million persons in Medicare had this supplemental insurance coverage for co-payments. (Id.) The proposed physician-administered class seeks to include health plans that provided MediGap insurance. Almost all health plans provide coverage for Medicare co-payments, so there is substantial overlap in membership among the classes. (Young Decl. ¶ 18.) There are more than four million Medicare enrollees

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[12] There may have been some variability from AWP in the basis for payment, since the seventeen regional carriers have the ability to change reimbursement in some situations. The number of regional carriers varied over the class period. There were thirty-five in 1991, and there are seventeen today. (Young ¶ 169.) Carriers may institute a "Least Costly Alternative" ("LCA") plan, wherein reimbursement for a particular drug may not be higher than that for a competitor drug. (Bell 34.) Such a plan was instituted by certain carriers for AstraZeneca's drug Zoladex, with the result being that reimbursement varied around the country, with some regions not basing reimbursement on Zoladex's AWP. (Bell 35; AstraZeneca Surreply at 2-3.) LCA started in 1997 in two states, and by 2002 had spread to forty states. (Schondelmeyer ¶ 41.) However, these variations appear to have been rare, and defendants have identified only the LCA plan for Zoladex as creating significant variation.

who do not have this supplemental MediGap insurance coverage and must pay their own coinsurance for Part B covered drugs. (Rosenthal 5.)

The benchmarks for Medicare Part B reimbursement were based on AWP even though the Department of Health and Human Services and other agencies have disclosed over the years that pharmacies' and providers' acquisition costs were typically less than AWP. (Berndt ¶ 65.) Moreover, various publications disclosed that physicians were able to purchase many of the Medicare Part B outpatient drugs at prices considerably less than AWP. (Berndt ¶ 97.) In Dr. Berndt's words, the existence of a spread "has not been a secret, at least to active observers and health care participants." (Berndt ¶ 65.) However, the parties dispute whether the government and industry were aware of the magnitude of the spread, and when they reasonably should have been aware of the spread.

2. The Private Reimbursement System for Self-Administered and Physician-Administered Drugs

TPPs include traditional insurance companies, health maintenance organizations ("HMOs"), other forms of ERISA plans, self-insured employers, and union benefit funds.

The system of private reimbursement by TPPs is complex and its characteristics vary depending on factors such as: (a) whether drugs were administered by a physician or were self-administered; (b) whether a PBM was used; and (c) whether a drug

was a single-source, brand-name drug or a multi-source, generic drug.

a. Self-Administered Drugs

In a typical single-source, self-administered drug transaction, a retailer, usually a pharmacy, purchases a drug from a wholesaler or manufacturer. The retailer sells the drug to a consumer-patient who has a prescription from a doctor. If the patient has prescription coverage through his employer, union or other entity, the retailer checks to see if the drug is on the formulary for the patient's insurance plan. If the drug is on the formulary, the patient usually pays a copayment, either based on a percentage of AWP or a flat copayment. The remainder of the payment is made by either a TPP or a PBM on behalf of the TPP. The patient self-administers the drug (e.g., by taking the pill).

i. PBMs

PBMs are the 800-pound gorillas of pharmaceutical reimbursement. They serve as middlemen, assisting TPPs in implementing their drug prescription programs. At least since the mid-1990s, PBMs have become pervasive in the market, as claims administrators, benefits advisors, and full-service providers (including mail-order and sometimes retail pharmacies). Some PBMs during the class period were stand-alone entities, while others were owned by managed care organizations (like Aetna and Anthem), retail pharmacies, grocery chains, wholesalers, or

drug manufacturers. (Berndt ¶ 127.)

According to Dr. Berndt, "[a]n important implication of the patterns of diversified ownership and heterogenous scale and scope of operations among PBMs is that commercial information regarding common negotiable contractual terms, such as rebates, discounts, audit rights, fee structure, penalties, risk assignment and other services offered is widely dispersed." (Berndt ¶ 133.) Plaintiffs' expert, Hartman, points out there is a lack of pricing transparency with respect to the precise details of PBM rebate contracts with manufacturers. (Hartman Decl. attach. C ¶ 24.) However, while the terms of a specific contract may be secret, "general knowledge concerning what is negotiable and what is the range of terms typically offered is widespread." (Berndt ¶ 134.)

Contracts between a health insurer, health plan, or self-insured employer and a PBM tend to be highly individualized, the result of negotiations that determine the best match of services for the plan. (Navarro ¶ 16.) At their most basic, PBMs may simply handle the administration of claims processing. This is how PBMs originally came about in the late 1980s. Over time, PBMs gained the capacity to handle more aspects of pharmaceutical reimbursement, including pharmacy network administration, formulary design and management, manufacturer rebate negotiation, drug utilization review (to determine whether a patient's

prescriptions may interact), physician communication and education (including formulary compliance incentives), mail-order pharmacy services, generic substitution plans, and assumption of risk (a PBM may contract to pay for some or all of the reimbursement of pharmaceuticals, or to do so after the plan pays a certain amount). (Bell 43; Navarro ¶ 20; Gaier Surreply ¶ 38.)

Generally speaking, a PBM does not directly purchase or take possession of a drug from a manufacturer, but rather acts as an intermediary (except with regard to the relatively small number of prescriptions dispensed through mail-order pharmacies). (Berndt ¶ 132; Schondelmeyer ¶ 76.) PBMs help to streamline administration, to enhance competition among parties providing products or services, such as pharmacies and drug manufacturers, and to create incentives for manufacturers to lower costs. These strategies can reduce pharmacy program costs by 25% to 30%. (Navarro ¶ 21.)

A TPP may purchase these services from a PBM or perform equivalent functions in-house. A TPP considering the use of a PBM will typically send out a request for proposals, describing its goals. Usually, several PBMs bid for these TPP contracts. Throughout the process, TPPs are commonly advised by benefits consulting companies like Segal Company, Towers Perrin and Mercer. In virtually all instances, self-insured employers and union benefit funds retain consultants to represent them in